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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 2001Q–0313]

Food Labeling: Health Claims; Soluble Dietary Fiber From Certain Foods and Coronary Heart Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is adopting as a final rule, without change, the provisions of the interim final rule that amended the regulation authorizing a health claim on the relationship between beta-glucan soluble fiber from whole oat sources and reduced risk of coronary heart disease (CHD). FDA is taking this action to complete the rulemaking initiated with the interim final rule.

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: James E. Hoadley, Center for Food Safety and Applied Nutrition (HFS–830), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1450.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of October 2, 2002 (67 FR 61773), the agency published an interim final rule to amend the regulation in part 101 (21 CFR part 101) that authorizes a health claim on the relationship between soluble dietary fiber from certain foods and reduced risk of CHD, to include an

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additional eligible source of whole oat beta-glucan soluble fiber, oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour. Under section 403(r)(3)(B)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(r)(3)(B)(i)), FDA issued this interim final rule in response to a petition filed under section 403(r)(4) of the act (21 U.S.C. 343(r)(4)). Section 403(r)(3)(B)(i) of the act states that the Secretary of Health and Human Services (the Secretary) (and, by delegation, FDA) shall issue a regulation authorizing a health claim only if he or she determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner which is consistent with generally recognized scientific procedures and principles), that there is significant scientific agreement, among experts qualified by scientific training and experience to evaluate such claims, that the claim is supported by such evidence (see also § 101.14(c)). Section 403(r)(4) of the act sets out the procedures that FDA is to follow upon receiving a health claim petition.

On April 21, 2001, the Quaker Oats Co. and Rhodia, Inc., (the petitioners) jointly filed a petition requesting that the agency amend the "soluble fiber from certain foods and coronary heart disease health claim" at § 101.81 to include a fourth source of beta-glucan soluble fiber eligible for the health claim. The petitioners requested that this amendment be made "with specific reference to the Quaker-Rhodia group oatrim, known as Oatrim (BETATRIM)" (Ref. 1). FDA filed the petition for comprehensive review in accordance with section 403(r)(4) of the act on July 20, 2001.

FDA considered the relevant scientific evidence presented in the petition as part of its review of the scientific literature on soluble fiber from the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour (referred to

as "oatrim") and CHD risk. The agency summarized this evidence in the interim final rule and determined that based on the available evidence: (1) CHD continues to be a disease for which the U.S. population is at risk; (2) soluble fiber from oatrim when used at levels providing 0.75 grams of beta-glucan soluble fiber per serving is a food because it provides nutritive value; (3) oatrim when used at levels necessary to justify the health claim is safe and lawful; (4) there is a physiological equivalence of beta-glucan soluble fiber from oatrim and beta-glucan soluble fiber from whole oat sources such as oat bran and rolled oats; and (5) there is significant scientific agreement, among qualified experts, that oatrim with a beta-glucan content of up to 10 percent on a dry weight basis (dwb) and not less than that of the starting material (dwb) may reduce the risk of CHD (67 FR 61773 at 61775 to 61779). Consequently, FDA published an interim final rule amending the health claim on the relationship between soluble dietary fiber from certain foods and reduced risk of CHD (§ 101.81) to include oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content of up to 10 percent on a dwb and not less than that of the starting material (dwb) as a source of oat beta-glucan soluble fiber eligible for the health claim.

II. Summary of Comments and the Agency's Response

FDA solicited comments on the interim final rule. The 75-day comment period closed on December 16, 2002. The agency received no comments in response to the interim final rule. Given the absence of contrary evidence on the agency's decisions announced in the interim final rule, FDA is adopting as a final rule, without change, the interim final rule that amended § 101.81 to add oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan soluble fiber content of up to 10 percent

on a dwb and not less than that of the starting material (dwb) as a substance eligible for the health claim.

III. Environmental Impact

The agency has determined under 21 CFR 25.32(p) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IV. Analysis of Impacts

A. Regulatory Impact Analysis

We have examined the economic implications of this final rule as required by Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity).

With this final rule, FDA is adopting, without change, the provisions of the interim final rule published in the **Federal Register** of October 2, 2002. The interim final rule amended the regulation authorizing a health claim on the relationship between beta-glucan soluble fiber from whole oat sources and reduced risk of CHD to include oatrim, the soluble fraction of alpha-amylase hydrolyzed oat bran or whole oat flour with a beta-glucan content up to 10 percent dwb and not less than that of the starting material (dwb). We assessed the costs and benefits of the interim final rule in that **Federal Register** document (67 FR 61773 at 61781). By now reaffirming that interim final rule,

FDA has not imposed any new requirements. There are, therefore, no additional costs and benefits associated with this final rule.

B. Regulatory Flexibility Analysis

We have examined the economic implications of this final rule as required by the Regulatory Flexibility Act (5 U.S.C. 601–612). If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires the agency to analyze regulatory options that would minimize the economic impact of the rule on small entities.

As this final rule does not make any changes to the interim final rule or our analysis included therein, this final rule does not impose any new costs on firms. Accordingly, we certify that this final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

C. Unfunded Mandates

Section 202(a) of the Unfunded Mandates Reform Act of 1995 (Public Law 104–4) requires that agencies prepare a written statement of anticipated costs and benefits before issuing any final rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 in any one year (adjusted annually for inflation). The Unfunded Mandates Reform Act does not require FDA to prepare a statement of costs and benefits for this rule, because the rule is not expected to result in any 1-year expenditure that would exceed $100 million adjusted for inflation. The current inflation-adjusted statutory threshold is $113 million.

V. Paperwork Reduction Act

FDA concludes that the labeling provisions of this final rule are not subject to review by the Office of Management and Budget because they do not

constitute a ''collection of information'' under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Rather, the food labeling health claim on the association between oatrim and reduced risk of CHD is a ''public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public'' (5 CFR 1320.3(c)(2)).

VI. Federalism

FDA has analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule has a preemptive effect on State law. Section 4(a) of the Executive order requires agencies to ''construe * * * a Federal Statute to preempt State law only where the statute contains an express preemption provision, there is some other clear evidence that the Congress intended preemption of State law, or where the exercise of State authority conflicts with the exercise of Federal authority under the Federal statute.'' Section 403A of the act (21 U.S.C. 343–1) is an express preemption provision. That section provides that ''no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce'' certain food labeling requirements, unless an exemption is provided by the Secretary (and by delegation, FDA). Relevant to this final rule, one such requirement that states and political subdivisions may not adopt is ''any requirement respecting any claim of the type described in section 403(r)(1) of the act made in the label or labeling of food that is not identical to the requirement of section 403(r) * * *'' (section 403A(a)(5) of the act (21 U.S.C. 343–1(a)(5)). Prior to the effective date of this rule and the interim final rule that preceded it, this provision operated to preempt States from imposing health claim labeling requirements concerning beta glucan soluble fiber from oatrim and reduced

risk of CHD because no such requirements had been imposed by FDA under section 403(r) of the act. Under this final rule and the interim final rule that preceded it, States are preempted from imposing any health claim labeling requirements for beta-glucan soluble fiber from oatrim and reduced risk of CHD that are not identical to those required by these rules. Section 403A(a)(5) of the act displaces both state legislative requirements and state common-law duties. *Medtronic* v. *Lohr*, 518 U.S. 470, 503 (1996) (Breyer, J., concurring in part and concurring in judgment); *id.* at 510 (O'Connor, J., joined by Rehnquist, C.J., Scalia, J., and Thomas, J., concurring in part and dissenting in part); *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion); *id.* at 548–49 (Scalia, J., joined by Thomas, J., concurring in judgment in part and dissenting in part). Although this final rule has preemptive effect in that it would preclude States from adopting statues, issuing regulations or adopting or enforcing any requirements including state tort-law requirements, about beta-glucan soluble fiber from oatrim and reduced risk of CHD that are not identical to the provisions of the interim final rule as adopted by this final rule, this preemptive effect is consistent with what Congress set forth in section 403A of the act.

Section 4(e) of the Executive order provides that "when an agency proposes to act through adjudication or rulemaking to preempt State law, the agency shall provide all affected State and local officials notice and an opportunity for appropriate participation in the proceedings." Similarly, section 6(e) of the Executive order states that "to the extent practicable and permitted by law, no agency shall promulgate any regulation that has federalism implications and that preempts state law, unless the agency, prior to the formal promulgation of the regulation *** consulted with State and local

officials early in the process of developing the proposed regulation." This requirement, that FDA provide the States with an opportunity for appropriate participation in this rulemaking, has been met. FDA sought input from all stakeholders through publication of the interim final rule in the **Federal Register**. There were no comments from State or local government entities received.

In conclusion, the agency believes that it has complied with all of the applicable requirements under the Executive order and has determined that the preemptive effects of this final rule are consistent with Executive Order 13132.

VII. References

The following reference has been placed on display at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. The Quaker Oats Co. and Rhodia, Inc., "Oatrim (BETATRIM) Health Claim Petition," HCN1, vol. 1, Docket No. 01Q–0313, April 12, 2001.

■ Accordingly, the interim final rule amending 21 CFR 101.81 that was published in the **Federal Register** of October 2, 2002 (67 FR 61773), is adopted as a final rule without change.

Dated: 7/21/03

July 21, 2003.

Jeffrey Shuren,
Assistant Commissioner for Policy.

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